

INDIANA IMMUNIZATION PROGRAM

STATEMENT OF POLICY

Title of Policy: **Refrigeration Standards
For Vaccine Storage**

Policy Number: II-02 (R2-07/2006)

Effective Date: April 1, 2006

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Purpose: This statement defines the standards that must be met when managing publicly supplied vaccine.

- Refrigerator/Freezer used for vaccine storage may either be a household- style or commercial-style. The freezer door is to be separate with a gasket door seal.
- **Dormitory type refrigerators have been shown to be unsuitable for the storage of vaccine and are not acceptable to CDC or the program.**
- A commercial or standard household refrigerator/freezer combination should be a minimum of 9.0 total Cubic Feet (cu ft.), with at least 6.6 cu ft. of refrigerator space and no less that 2.4 cu ft freezer compartment with separate doors and intact door seal gaskets.
- Separate refrigerator units must be at least 4.9 cu ft. with intact sealing door gaskets.
- Separate freezer units must be at least 3.0 cu. ft. with intact sealing door gaskets.
- Temperature logs must be maintained for both refrigerator and freezer compartments of any units used to store vaccine. Entries are required twice daily during regular business hours. It is recommended that temperatures be checked and recorded first thing when the practice opens and at the end of the day. These logs must be kept for three years.
- Refrigerators must maintain a temperature range from 2°C to 8°C (35° to 46° F.).
- **Freezers must maintain a temperature range at -15 degrees C (5 degrees F.) or lower.**
- Place vaccine and thermometers in the center area of the refrigerator/freezer.
- Thermometers must be calibrated certified traceable by National Institute of Standards and Technology (NIST) standards. The preferred thermometers are the Refrigerator Exact Temperature Spirit Thermometer (Fisher #15-059-337) and the Freezer Exact Temperature Spirit Thermometer (Fisher #15-059-338) or comparable.

- If a temperature is recorded **above** or **below** the recommended range do not use the vaccine until the following steps are taken and the viability of the vaccine has been established.
 1. Immediately check the thermometer for correct placement and operation.
 2. Move the vaccine to suitable locations to maintain the cold chain.
 3. Contact the manufacturer of each affected vaccine.
 4. Contact the ISDH Immunization Program (317-233-7704).
- Keep extra containers of water (labeled “Not for Consumption”) in the refrigerator and ice packs in the freezer to maintain temperature.
- Vaccines cannot be stored in the refrigerator/freezer doors or drawers.
- Each circuit breaker/fuse box controlling the circuit for all refrigerator/freezers containing vaccine must be marked with a sign warning against shutting off the switch.
- No food, drink, or lab specimen is to be stored in the refrigerator/freezer where vaccine is stored.
- Any accessible receptacle having a plug for a refrigerator and/or freezer, which contain vaccine, must have posted on the wall, immediately next to receptacle, a sign warning not to pull this particular plug. If receptacle is not accessible, then the sign must be posted on the outside door of refrigerator and/or freezer. This sign must display the following words, "Do Not Unplug. Expensive Vaccine in Storage."
- Vaccine must be rotated, with vaccines with the shortest expiration dates placed in the front of the other lots of the same vaccine with longer expiration dates.
- All instances of suspected vaccine spoilage due to failure to maintain the cold chain must be reported to the Indiana State Department of Health (ISDH) Immunization Program as soon as possible at 800-701-0704. An incident report will be forwarded from the program and must be completed and returned by the provider within 10 business days of the event.
- Each facility must have emergency procedures for the handling of vaccine in the event of power or equipment failure. (see attached guidelines)
- Publicly funded vaccine must be designated as separate vaccine stock from privately funded vaccine by the use of stickers/labeling or a distinct shelf or section of the refrigerator/freezer.
- Keep vaccines in their original cardboard boxes with lids intact to protect from light.
- Appeals can be made directly to the Immunization Program Director.